IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.	:	
Plaintiffs,	:	
v.	:	**Civil Action No. 05-356 (KAJ)**
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	
Defendants.	:	

ANSWER OF DEFENDANT
TEVA PHARMACEUTICAL INDUSTRIES LTD.

Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") answers the Complaint of Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. (collectively, "Plaintiffs") as follows:

1. Teva Ltd. states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 of the Complaint, and on that basis denies the allegations set forth therein.

2. Teva Ltd. states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint, and on that basis denies the allegations set forth therein.

3. Teva Ltd. states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint, and on that basis denies the allegations set forth therein.

4. Teva Ltd. admits that Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation incorporated and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania, 19454. Teva Ltd. denies the remaining allegations set forth in Paragraph 4 of the Complaint.

5. Teva Ltd. admits that it is a foreign corporation organized and existing under the laws of Israel and having a principal place of business in Israel. Teva Ltd. further admits that Teva USA is a wholly owned indirect subsidiary of Teva Ltd.

6. Teva Ltd. admits that Teva USA filed an abbreviated new drug application ("ANDA") No. 77-587 for galantamine hydrobromide tablets. Teva Ltd. further admits that portions of Teva USA's ANDA No. 77-587 are derived from information Teva Ltd. provided Teva USA. Teva Ltd. further admits that, in the event that the United States Food and Drug Administration ("FDA") approves Teva USA's ANDA, Teva USA intends to market and sell such galantamine hydrobromide tablets. Teva Ltd. further admits that Teva USA markets and sells pharmaceutical products, including generic prescription drug products manufactured and sold pursuant to approved ANDAs. Teva Ltd. denies the remaining allegations set forth in Paragraph 6 of the Complaint.

7. Teva Ltd. admits that Plaintiffs filed a civil action asserting patent infringement arising under Title 35 of the United States Code, for alleged infringement of United States Patent No. 4,663,318 ("the '318 patent"). Teva Ltd. denies that Plaintiffs' claims are valid or have merit. Teva Ltd. further admits this Court has subject matter jurisdiction over patent

infringement claims under 28 U.S.C. §§ 1331 and 1338(a) but denies that the Complaint states a legally cognizable claim for patent infringement against Teva Ltd.

8. The allegations contained in Paragraph 8 of the Complaint are not directed to Teva Ltd. and, accordingly, no response is required.

9. Teva Ltd. denies that this Court has personal jurisdiction over Teva Ltd. for the purposes of this action.

10. Teva Ltd. denies that venue is proper in this judicial district with respect to Teva Ltd.

11. Teva Ltd. admits that to introduce a drug that has not previously been approved by the FDA into interstate commerce, a new drug application ("NDA") must be submitted to the FDA, including information required under 21 U.S.C. § 355(b). Teva Ltd. otherwise denies the allegations set forth in Paragraph 11 of the Complaint to the extent they are inconsistent with the law. Teva Ltd. further denies the remaining allegations set forth in Paragraph 11 of the Complaint.

12. Teva Ltd. admits that an abbreviated application process is available for approval to market a generic version of a listed drug, and that an abbreviated new drug application ("ANDA") must include information required under 21 U.S.C. § 355(j). Teva Ltd. further admits that whether the FDA will consider a drug to be bioequivalent to a listed drug is at least partially governed by 21 U.S.C. § 355(j). Teva Ltd. otherwise denies the allegations set forth in Paragraph 12 of the Complaint to the extent they are inconsistent with the law.

13. Teva Ltd. admits that 21 U.S.C. § 355(j) does not require that an ANDA contain all of the same information required in an NDA. Teva Ltd. further admits that 21 U.S.C. § 355(j) at least partially governs what information must be included in an ANDA. Teva Ltd. otherwise

denies the allegations set forth in Paragraph 13 of the Complaint to the extent they are inconsistent with the law. Teva Ltd. further denies the remaining allegations set forth in Paragraph 13 of the Complaint.

14. Teva Ltd. admits that according to 21 U.S.C. § 355(j), an ANDA must contain information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug. Teva Ltd. otherwise denies the allegations set forth in Paragraph 14 of the Complaint to the extent they are inconsistent with the law.

15. Teva Ltd. admits that according to 21 U.S.C. § 355(a), no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to 21 U.S.C. § 355(b) or (j) is effective with respect to such drug. Teva Ltd. otherwise denies the allegations set forth in Paragraph 15 of the Complaint to the extent they are inconsistent with the law.

16. Teva Ltd. admits that Janssen Pharma is identified by the FDA as the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of Eq. 4 mg base, 8 mg base, and 12 mg base. Teva Ltd. further admits that February 28, 2001 is the date identified by the FDA as the date on which NDA No. 21-169 was approved. Teva Ltd. further admits that the sole indication of use for which galantamine hydrobromide tablets are approved by the FDA in NDA No. 21-169 is the treatment of mild to moderate dementia of the Alzheimer's type. Teva Ltd. denies the remaining allegations set forth in Paragraph 16 of the Complaint.

17. Teva Ltd. admits that a commercial formulation of galantamine hydrobromide approved by the FDA for the treatment of mild to moderate dementia of the Alzheimer's type is sold under the trademarks RAZADYNE® and/or REMINYL®. Teva Ltd. states that it is without

knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 17 of the Complaint, and on that basis denies the allegations set forth therein.

18. Teva Ltd. admits that the '318 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") in connection with NDA No. 21-169.

19. Teva Ltd. admits it has not previously challenged the listing of the '318 patent in the Orange Book. Teva Ltd. denies that the '318 patent has any valid claims for an approved use of the drug product that is the subject of NDA No. 21-169 such that it qualifies for listing in the Orange Book. Teva Ltd. further denies the remaining allegations set forth in Paragraph 19 of the Complaint.

20. Teva Ltd. admits that Teva USA has represented that on or before April 22, 2005, Teva USA submitted to the FDA ANDA No. 77-587 and paragraph IV certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) for galantamine hydrobromide tablets bioequivalent to the commercial formulation of galantamine hydrobromide marketed under the trademarks RAZADYNE® and/or REMINYL®. Teva Ltd. further admits that Teva USA filed the ANDA and paragraph IV certifications to obtain approval under 21 U.S.C. § 505(j) to engage in the commercial manufacture and sale of Teva USA's proposed galantamine hydrobromide tablets before the expiration of the patents listed in the Orange Book for NDA No. 21-169. Teva Ltd. further admits that if Teva USA obtains such approval from the FDA for ANDA No. 77-587 Teva USA intends to market in the United States the galantamine hydrobromide products described in the ANDA, and that such marketing may occur before the expiration of the '318 patent. Teva Ltd. denies the remaining allegations set forth in Paragraph 20 of the Complaint.

21. Teva Ltd. admits that the condition of use for which Teva USA seeks approval in its ANDA No. 77-587 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in NDA No. 21-169. Teva Ltd. denies the remaining allegations set forth in Paragraph 21 of the Complaint.

22. Teva Ltd. admits that the indication set forth in the proposed labeling submitted by Teva USA in its ANDA No. 77-587 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for the commercial formulation of galantamine hydrobromide which is marketed under the trademarks RAZADYNE® and/or REMINYL®. Teva Ltd. denies the remaining allegations set forth in Paragraph 22 of the Complaint.

23. Teva Ltd. realleges its responses to the allegations contained in Paragraphs 1-22 above as if fully set forth herein.

24. Teva Ltd. admits that the '318 patent is entitled "Method of Treating Alzheimer's Disease" and states on its face that it was issued May 5, 1987. Teva Ltd. states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 24 of the Complaint, and on that basis denies the remaining allegations.

25. Teva Ltd. states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 25 of the Complaint, and on that basis denies the allegation set forth therein.

26. Teva Ltd. admits that a commercial formulation of galantamine hydrobromide is marketed under the trademarks RAZADYNE® and/or REMINYL®. Teva Ltd. denies that the conditions of use for which the commercial formulation of galantamine hydrobromide is

approved falls within one or more valid claim of the '318 patent. Teva Ltd. states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 26 of the Complaint, and on that basis denies the remaining allegations set forth therein.

27. Teva Ltd. states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27 of the Complaint, and on that basis denies the allegations set forth therein.

28. Teva Ltd. denies the allegations set forth in Paragraph 28 of the Complaint.

29. Teva Ltd. denies the allegations set forth in Paragraph 29 of the Complaint.

30. Teva Ltd. denies the allegations set forth in Paragraph 30 of the Complaint.

31. Teva Ltd. denies the allegations set forth in Paragraph 31 of the Complaint.

32. Teva Ltd. admits that it had knowledge of the '318 patent prior to Teva USA filing ANDA No. 77-587. Teva Ltd. denies that this knowledge can or does form the basis for a finding of willful infringement as to Teva Ltd. and as such denies the remaining allegations set forth in Paragraph 32 of the Complaint.

33. Teva Ltd. denies the allegations set forth in Paragraph 33 of the Complaint.

First Defense

34. The manufacture, use, offering for sale, sale or importation of the galantamine hydrobromide tablets that are the subject of ANDA No. 77-587 will not infringe directly or indirectly any valid claim of the '318 patent.

35. Teva USA's filing of its ANDA No. 77-587 did not infringe any valid claim of the '318 patent.

Second Defense

36. Each claim of the '318 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code.

Third Defense

37. At least one of the Plaintiffs lacks standing to assert infringement of the '318 patent by Teva Ltd.

Fourth Defense

38. The Complaint fails to state a claim against Teva Ltd. on which relief can be granted.

Fifth Defense

39. This Court lacks personal jurisdiction over Teva Ltd.

PRAYER FOR RELIEF

WHEREFORE, defendant Teva Pharmaceutical Industries Ltd. respectfully requests that:

a) The Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. be dismissed with prejudice;

b) The Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. be dismissed for lack of personal jurisdiction;

c) The filing of Teva USA's ANDA No. 77-587 be found not to infringe any valid claims of the '318 patent;

d) The manufacture, use, offering for sale, sale or importation into the United States of Teva USA's galantamine hydrobromide tablets that are the subject of Teva USA's ANDA No. 77-587 be found not to infringe any valid claims of the '318 patent;

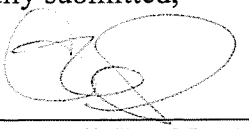
e) The '318 patent be found invalid;

f) Teva Ltd. be awarded its costs in this action;

g) Teva Ltd. be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and

h) Teva Ltd. be awarded such other and further relief as this Court may deem just and proper.

Respectfully submitted,



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Dated: August 10, 2005

CERTIFICATE OF SERVICE

I, Adam W. Pofff, Esquire, hereby certify that on August 10, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on August 10, 2005, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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